

within three months of the goal date, extends the goal date by three months. A major amendment to a manufacturing supplement submitted within two months of the goal date extends the goal date by two months.

C. A resubmitted original application is a complete response to an action letter addressing all identified deficiencies.

D. Class 1 resubmitted applications are applications resubmitted after a complete response letter (or a not approvable or approvable letter) that include the following items only (or combinations of these items):

1. Final printed labeling
2. Draft labeling
3. Safety updates submitted in the same format, including tabulations, as the original safety submission with new data and changes highlighted (except when large amounts of new information including important new adverse experiences not previously reported with the product are presented in the resubmission)
4. Stability updates to support provisional or final dating periods
5. Commitments to perform Phase 4 studies, including proposals for such studies
6. Assay validation data
7. Final release testing on the last 1-2 lots used to support approval
8. A minor reanalysis of data previously submitted to the application (determined by the agency as fitting the Class 1 category)
9. Other minor clarifying information (determined by the Agency as fitting the Class 1 category)
10. Other specific items may be added later as the Agency gains experience with the scheme and will be communicated via guidance documents to industry.

E. Class 2 resubmissions are resubmissions that include any other items, including any item that would require presentation to an advisory committee.

F. A Type A Meeting is a meeting which is necessary for an otherwise stalled drug development program to proceed (a "critical path" meeting).

G. A Type B Meeting is a 1) pre-IND, 2) end of Phase 1 (for Subpart E or Subpart H or similar products) or end of Phase 2/pre-Phase 3, or 3) a pre-NDA/BLA meeting. Each requestor should usually only request 1 each of these Type B meetings for each potential application (NDA/BLA) (or combination of closely related products, i.e., same active ingredient but different dosage forms being developed concurrently).

H. A Type C Meeting is any other type of meeting.

I. The performance goals and procedures also apply to original applications and supplements for human drugs initially marketed on an over-the-counter (OTC) basis through an NDA or switched from prescription to OTC status through an NDA or supplement.

LOCAL LAW ENFORCEMENT ACT OF 2001

Mr. SMITH of Oregon. Mr. President, I rise today to speak about hate crimes legislation I introduced with Senator KENNEDY in March of last year. The Local Law Enforcement Act of 2001 would add new categories to current hate crimes legislation sending a signal that violence of any kind is unacceptable in our society.

I would like to describe a terrible crime that occurred July 23, 2001 in Thibodaux, LA. A black woman was shot in the face with a paintball gun

outside her home. Two teens were arrested and charged for aggravated battery in what police called a hate crime. The assailants were heard to have made comments about "wanting to shoot black people."

I believe that government's first duty is to defend its citizens, to defend them against the harms that come out of hate. The Local Law Enforcement Enhancement Act of 2001 is now a symbol that can become substance. I believe that by passing this legislation and changing current law, we can change hearts and minds as well.

TRIBUTE TO THE HEROES OF D-DAY

Mr. BAUCUS. Mr. President, I rise today in commemoration of the 58th anniversary of the largest air, land, and sea invasion ever undertaken: D-Day.

This monumental task involved over 150,000 American, British, Canadian, Free French, and Polish troops. Each of these individuals took great risks, sacrificing themselves for the sake of freedom and democracy.

For many of the Americans storming the Utah and Omaha beach, D-Day offered their first glimpse of the enemy and death. Although, there had been extensive training and planning of the invasion, this was a challenge unlike any other. Facing incredible odds, natural obstacles and man-made fortifications, the allied troops secured a beachhead in Nazi occupied Europe from which to begin a western frontal attack. D-Day was a colossal moment where freedom and democracy regained a foothold in Europe at the cost of many brave individuals.

There are many heroes of D-Day; many we honored and remembered just a little over a week ago during Memorial Day weekend and others who are passing each day. I know it is my wish, as it must be for the other members of this body, that the valor and sacrifices of our Nation's fighting men and women are not forgotten. Each generation deserves to understand the important events that shaped the world we live in. I'm happy to see construction underway with the World War II monument on the National Mall. This will serve as another reminder to those of today and tomorrow of those who came before us and made, "For God and Country," the ultimate sacrifice.

On the anniversary of possibly the most difficult military invasion, I tip my hat in solemn remembrance to those who fought so bravely to protect freedom and liberty here and abroad. I also ask that all Americans take a moment to remember their sacrifices, which allowed the world to enjoy a greater freedom.

In conclusion, it is evident that following the savage attacks of September 11, new sacrifices lay ahead of us. As America rises to meet these challenges we can take solace in the model of courage and determination of

those who gave their lives on the beaches of Normandy to protect our freedom.

Mr. JOHNSON. Mr. President, on this day 58 years ago, Allied forces began the D-Day invasion of Normandy, France. Given the importance of this event to our nation's history, we should take a moment today to remember and to honor those who sacrificed their lives on the beaches of France in the fight against the forces of fascism.

D-Day was the largest air, land, and sea invasion in history. More than 5,000 ships, 10,000 airplanes, and 150,000 troops participated in the invasion of June 6, 1944. Soldiers from America, Britain, Canada, and France worked in concert to storm the beaches of Normandy, overcome entrenched German defensive positions, and establish a beachhead from which France and all of Europe was liberated. The success of the D-Day invasion not only turned the tide of the war, but changed the course of history as well.

Exact casualties from the invasion have proven difficult to calculate. But upwards of 10,000 men were killed or wounded on the five beaches whose code names we have all come to know so well: Utah, Omaha, Gold, Juno, and Sword.

Today, we pause to honor all of those who participated in the Normandy invasion, including those who were killed, those who have died in the six decades since the invasion, and those who survive today to tell of their comrades' bravery and sacrifices. We owe a debt to each of these men that can never be fully repaid. Yet, I believe one of the best ways for us to pay our respect to these heroes, is to honor our commitments to our veterans and to those serving in the active duty and reserve.

In an attempt to thank the U.S. servicemembers who participated in the liberation of France, the French government is offering certificates to U.S. veterans who served in France, its territorial waters, or airspace between June 6, 1944 and May 8, 1945. I am working to make my constituents aware of these Thank-You-America Certificates so that all eligible South Dakota veterans get the recognition for their service that they deserve.

I know that my colleagues will join with me in commemorating the 58th anniversary of the D-Day invasion and honoring the veterans who answered our Nation's call to service on that fateful day.

ADDITIONAL COSPONSOR TO S. RES. 281

Mr. LEVIN. Mr. President, I ask unanimous consent that the Senator from Iowa, Mr. GRASSLEY, be added as a cosponsor to S. Res. 281. I ask unanimous consent that the RECORD to reflect that Senator GRASSLEY was inadvertently left off the list of original cosponsors to S. Res. 281 due to an error.